DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

February 20, 2001

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 01-27

Grant Van Dyk, Co-Owner
Van Dyk Holsteins
1450 Van Dyk Road
Lynden, Washington 98264

WARNING LETTER

Dear Mr. Van Dyk:

An investigation at your dairy located at 1450 Van Dyk Road Lynden, Washington by our investigator on December 19 through December 22, 2000, confirmed that you offered an animal for sale for slaughter as food in violation of Section 402(a)(2)(C)(ii), and 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act).

A food is adulterated under Section 402(a)(2)(C)(ii) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512 of the Act. On or about October 18, 2000, you sold a culled dairy cow identified on USDA-FSIS laboratory report # 411559, also identified with back tag # 91 FX 5069, for slaughter as human food to [redacted] USDA analysis of tissue samples collected from that animal identified the presence of gentamicin in the kidney at 19.55 parts per million (ppm). There is no allowable tolerance for gentamicin in the edible tissue of cattle.

A food is adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions...whereby it may have been rendered injurious to health." As it applies in this case, "insanitary conditions" means that you hold animals which are ultimately offered for sale for slaughter as food under conditions which are so inadequate that medicated animals bearing possibly harmful drug residues are likely to enter the food supply.

For example, our investigator noted the following conditions on your farm:

1. You lack an adequate system for identifying which animals have been treated including the date of treatment, the drug administered, the quantity of drug administered, the route of administration, and the drugs pre-slaughter withdrawal time.
2. You lack an adequate system for assuring animals have been treated only with drugs which have been approved for use in their class of animal or species, in that your veterinarian advised you that Gentocin use could result in gentamicin residue for up to 18 months.

We request that you take prompt action to ensure that dairy cows and calves which you offer for sale as human food will not be adulterated with drugs or contain illegal residues.

Introducing adulterated foods into interstate commerce is a violation of Section 301(a) of the Act. Causing the adulteration of drugs after receipt in interstate commerce is a violation of Section 301(k) of the Act.

You should be aware that it is not necessary for you to have personally shipped an adulterated animal into interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated animal to be slaughtered into food for human consumption where it was held for sale in interstate commerce is sufficient to make you responsible for violations of the Act.

Our investigation revealed that the gentamicin residue came from your use of Gentocin, 50mg/mL on your dairy herd. Gentamicin is not approved for use on dairy cows without a written prescription. Although you had an old prescription for Gentocin, it was not issued for the treated cow, and your veterinarian had advised you that use of Gentocin could result in gentamicin residue for up to 18 months. Your use of Gentocin can be considered off label use which is a deviation from Title 21, Code of Federal Regulations (21 CFR), Part 530.

In October of 1994, Congress passed the Animal Medicinal Drug Use Clarification Act, which permits extra-label use under certain controlled conditions, specified in 21 CFR Part 530. Extra label use is only permitted if the use is by or on the lawful order of a licensed veterinarian within the context of a valid veterinarian/client/patient relationship and in conformance with criteria set forth in Part 530.

We also note that this is not your first tissue residue violation. You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction.

Within fifteen (15) days of the receipt of this letter, notify this office in writing of the specific steps you have taken to correct these violations and preclude their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which corrections will be completed.

Please send your reply to the Food and Drug Administration, Attention: Bruce Williamson, Compliance Officer, 22201 23rd Drive SE, Bothell, WA 98021. If you have questions regarding any issue in this letter, please contact Bruce Williamson, Compliance Officer, (425) 483-4976.

Sincerely,

Charles M. Breen
District Director

Enclosure:
Form FDA 483

CC: Dr. Ahmed/USDA/FSIS/Tissue Residue
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1299 Farnam St.
Omaha, Nebraska 68102